



## First ultrasound diagnosis of BI-RADS 3 lesions in young patients: Can 6-months follow-up be sufficient to assess stability?



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### ABSTRACT

**Objectives:** To evaluate the outcome of repeated short-term follow-up with ultrasound in no high-risk young patients with a BI-RADS3 lesion at first examination.

**Methods:** In this IRB-approved study 492 women, aged 18–34 years (mean  $\pm$  standard deviation,  $28 \pm 4.5$  years) with first breast ultrasound examination in 2012–2014 were retrospectively evaluated. Inclusion criteria were: at least one BI-RADS3 lesion and (a) biopsy/surgical excision or (b) follow-up of at least 18 months (including a 6-month follow-up). BI-RADS category assigned during follow-up and pathologic findings in cases undergoing biopsy/surgical excision were collected. At the 6- and 18-month follow-up the recommended biopsy rates (RBR) and the corresponding positive predictive value (PPV) were calculated.

**Results:** In 97 patients, 151 BI-RADS3 lesions were identified. Biopsy/surgical excision was initially performed in 25/151 (16.5%) lesions. After 6-month, category was downgraded to BI-RADS1/2 in 23/126 (15.3%) and upgraded to BI-RADS4 in 9/126 lesions (7.1%). Pathological diagnosis of these lesions was fibroadenoma in 5 and benign phyllodes tumor in 4 cases (RBR 7%, PPV<sub>bio</sub> 44.4%). After 18-month one lesion was classified BI-RADS4 and pathological diagnosis was fibroadenoma (RBR 1.1%, PPV<sub>bio</sub> 0%).

**Conclusions:** Our preliminary data show that follow-up imaging performed after 18 months from a first BI-RADS3 diagnosis does not affect clinical treatment and 6-month follow-up may be sufficient to assess the stability of probably benign lesions.

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### 1. Introduction

According to the Breast Imaging Reporting and Data System (BI-RADS), category 3 is assigned to probably benign lesions, for which a likelihood of malignancy of less than 2% has been proven at mammography and in most of ultrasound (US) studies [1–7]. Management of these lesions by means of surveillance (i.e. 6-, 12- and 24- month follow-up examinations) as an alternative to the more expensive and invasive percutaneous imaging-guided tissue sampling, rests on the demonstration that probably benign lesions

exhibit a very low likelihood of malignancy and that the follow-up will establish the progression of those actually malignant. Moreover, diagnosis of these malignancies during the surveillance will occur in an early phase of their course corresponding to a still favorable prognosis [2,3,8]. At US breast imaging, BI-RADS category 3 is specifically applied in case of hypoechoic circumscribed, oval solid masses, parallel to the skin, mostly fibroadenoma, as well as in case of isolated, complicated cysts with uniform low-level echoes and clustered microcysts in the form of microlobulated or oval masses [1].

Apart from conditions at increased risk for breast cancer (e.g. women with known mutation or genetic syndrome with increased breast cancer risk), in women younger than 30 years with breast symptoms or undergoing voluntary screening, ultrasound examination is usually recommended instead of mammography because of its lack of ionizing radiation and decreased sensitivity of mammography in dense breasts, frequently observed in this category of women [9–12]. Moreover, previous studies in young women have shown that breast ultrasound exhibits a sensitivity of 100%

**Abbreviations:** BI-RADS, Breast Imaging Reporting and Data System; US, Ultrasound; PPV, positive predictive value; PPV<sub>bio</sub>, positive predictive value for biopsy performed after recommendation due to interval changes.

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in the detection of breast malignancy also in case of symptomatic patients, supporting the selective use of mammography for highly suspicious ultrasound cases [10,13].

Even in presence of breast symptoms, breast cancer is rare in young patients with 2.4% of breast cancers diagnosed in women younger than 35 years and 1% in women younger than 30 years [14,15]. Considering the low incidence of breast cancer in young women and negative effects of repeated follow-up examinations, such as anxiety and costs of additional imaging, the proved lesion stability at the short-term follow-up performed after 6 months from initial diagnosis may be adequate to support benignity of the lesions. To our knowledge there are no previous studies focusing on the optimal management of probably benign lesions in young patients. Therefore, the purpose of our study was to retrospectively evaluate the outcome of repeated short-term follow-up with ultrasound in patients younger than 35 years with a BI-RADS 3 lesion at first ultrasound examination and proven lesion stability at the 6-month follow-up.

## 2. Materials and methods

### 2.1. Study participants

This is a retrospective study with institutional review board approval. Informed consent was waived. We identified 492 consecutive women aged between 18 and 34 years (mean age  $\pm$  standard deviation,  $28 \pm 4.5$  years) who underwent their first US examination between July 2012 and June 2014 at our institution. Inclusion criteria were as follows: (1) at least one lesion with BI-RADS category 3 assigned at the first ultrasound examination; (2) biopsy or surgical excision or follow-up of at least 18 months. The following exclusion criteria were applied: (1) presence of a lesion with a more severe BI-RADS assessment elsewhere in either breast in the same patient; (2) presence of solely typically benign findings i.e. benign cysts or intramammary lymph nodes (BI-RADS 2); (3) absence of findings (BI-RADS 1); (4) patients at high risk for breast cancer (i.e. two or more first- or second-degree relatives with breast or ovarian cancer, premenopausal breast cancer in a close relative, proven BRCA1 or BRCA2 mutation in patient or first-degree relatives, male relatives with breast cancer) or with a history of other malignancies.

Following patients' characteristics were evaluated: (a) presence of clinical manifestation (i.e. palpable mass either self-discovered or found by referring clinician, mastodynia, nipple discharge.); (b) family history of breast cancer apart from the above criteria for high risk.

### 2.2. Ultrasound imaging

At our institution, for all women younger than 40 years, US examination represents the primary imaging modality either in a screening setting or in presence of breast symptoms. BI-RADS US lexicon is applied for reporting.

US examinations were performed by four different attending radiologists with at least 5 years experience in breast imaging. A Logiq E9 ultrasound system (GE Healthcare, Milwaukee, WI, USA) equipped with a linear 6–15 MHz probe was used for the examinations. The protocol applied in case of first diagnosis of a BI-RADS 3 lesion includes a 6-month follow-up and, in case of lesion stability, a subsequent follow-up after 18 months from the first diagnosis. No controls are performed after 12 months from the first diagnosis. At the 18-month control, assuming the mass is stable, BI-RADS 2 category is usually assigned. Despite a BI-RADS 3 category recommendation, a biopsy can be performed at each stage according to the patient's preference, the referring physician's or the attending radiologist's recommendation.

Patient records were used for identification and analysis of cases and no radiological reading of US images was performed. Imaging studies performed after the first US examination were grouped into two time intervals: US studies performed after 4–9 months were considered 6-month follow-up whereas US studies performed 15–21 months were considered 18-month follow-up.

For each mass the following features were analyzed: size (at least two diameters), shape, orientation, margins, echo pattern, posterior features, and vascularity. When the mass was entirely composed of clustered microcysts or consisting of a complicated cyst with uniform low-level echoes no additional descriptors were used apart from the size.

To assess for interval change after the first ultrasound examination, each imaging report was read and if no change was noted, "no interval change" was entered. In case of any lesion variation supporting the recommendation to biopsy the case was recorded as "interval change" and the finding that led to biopsy was reported. Biopsy was performed for every case in which BI-RADS assessment was changed to category 4 during the follow-up due to any suspicious variation (e.g. border characteristics) or size increase. Generally, biopsy of the lesion is recommended when an increase of more than 20% is observed in at least two of three dimensions. In cases with less increase, the decision to recommend biopsy is left to the reporting radiologist [16]. In our analysis, the diameter with the greatest increase was recorded for comparison and the percentage of increase (%D) was calculated as follows:  $\%D = (D2 - D1) \times 100 / D1$ , where D1 represents the diameter with greatest increase at the first control and D2 the corresponding diameter at the follow-up. In case of lesions which decreased by more than 20% in at least two of three dimensions or resolved at the 6-month follow-up, BI-RADS 2 or 1 category was assigned and further follow-up was not required [1].

In BI-RADS 3 category lesions which underwent biopsy, motivation was sought in the report. For all cases undergoing biopsy, presence of 6 or 12 months US examination after the biopsy was evaluated, except when surgical excision was performed.

### 2.3. Statistical analysis

Normal distribution of the data was confirmed visually on the histogram. Independent samples *t*-test was used to compare age in patients with BI-RADS 3 lesions versus patients with other than BI-RADS 3 lesion and lesion size corresponding to the different histological diagnoses. Proportions (i.e. percentage of cases with clinical palpable mass or family history in patients with BI-RADS 3 lesions versus patients with other than BI-RADS 3 lesion) compared using  $\chi^2$  test.

Recommended biopsy rates at the 6-month and 18-month follow-up were calculated by dividing the number of lesions rated as BI-RADS 4 by the total number of lesions with follow-up at each time interval. The positive predictive value (PPV) for biopsy performed after recommendation due to interval changes ( $PPV_{bio}$ ) corresponds to the number of detected malignancies or high risk lesions divided by the total number of cases with a recommendation to biopsy at the corresponding interval follow-up.

All *P* values were two-sided and significance level was 0.05. Statistical analyses were performed with SPSS (SPSS, release 22.0, Chicago, IL USA).

## 3. Results

### 3.1. BI-RADS category 3 occurrence and lesions US characteristics

Among the 492 consecutive young women undergoing their first breast US examination, 146 patients had at least a lesion classified as BI-RADS 3 (Fig. 1). Forty-nine patients (33.6%) did not complete

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